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(Original Signature of Member)

111TH CONGRESS  
1ST SESSION

**H. R.** \_\_\_\_\_

To amend the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Federal Food, Drug, and Cosmetic Act to provide for improved public health and food safety through enhanced enforcement, and for other purposes.

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**IN THE HOUSE OF REPRESENTATIVES**

Ms. DEGETTE introduced the following bill; which was referred to the  
Committee on \_\_\_\_\_

\_\_\_\_\_  
**A BILL**

To amend the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Federal Food, Drug, and Cosmetic Act to provide for improved public health and food safety through enhanced enforcement, and for other purposes.

1       *Be it enacted by the Senate and House of Representa-*  
2       *tives of the United States of America in Congress assembled,*

3       **SECTION 1. SHORT TITLE.**

4       This Act may be cited as the “Safe And Fair En-  
5       forcement and Recall for Meat, Poultry, and Food Act of

1 2009” or “SAFER Meat, Poultry, and Food Act of  
2 2009”.

3 **SEC. 2. FOOD SAFETY ENFORCEMENT FOR MEAT AND MEAT**  
4 **FOOD PRODUCTS.**

5 (a) IN GENERAL.—The Federal Meat Inspection Act  
6 (21 U.S.C. 601 et seq.) is amended—

7 (1) by redesignating section 411 (21 U.S.C.  
8 680) as section 414; and

9 (2) by inserting after section 410 (21 U.S.C.  
10 679a) the following:

11 **“SEC. 411. NOTIFICATION, NONDISTRIBUTION, AND RECALL**  
12 **OF ADULTERATED OR MISBRANDED ARTI-**  
13 **CLES.**

14 “(a) NOTIFICATION TO SECRETARY OF VIOLATION.—

15 “(1) IN GENERAL.—A person (other than a  
16 household consumer) that has reason to believe that  
17 any carcass, part of a carcass, meat, or meat food  
18 product of cattle, sheep, swine, goats, horses, mules,  
19 or other equines (referred to in this section as an  
20 ‘article’) transported, stored, distributed, or other-  
21 wise handled by the person is adulterated or mis-  
22 branded shall, as soon as practicable, notify the Sec-  
23 retary of the identity and location of the article.

24 “(2) MANNER OF NOTIFICATION.—Notification  
25 under paragraph (1) shall be made in such manner

1 and by such means as the Secretary may require by  
2 regulation.

3 “(b) RECALL AND CONSUMER NOTIFICATION.—

4 “(1) VOLUNTARY ACTIONS.—On receiving noti-  
5 fication under subsection (a) or by other means, if  
6 the Secretary finds that an article is adulterated or  
7 misbranded and that there is a reasonable prob-  
8 ability that human consumption of the article would  
9 present a threat to public health (as determined by  
10 the Secretary), the Secretary shall provide all appro-  
11 priate persons (as determined by the Secretary),  
12 that transported, stored, distributed, or otherwise  
13 handled the article with an opportunity—

14 “(A) to cease distribution of the article;

15 “(B) to notify all persons that transport,  
16 store, distribute, or otherwise handle the article,  
17 or to which the article has been transported,  
18 sold, distributed, or otherwise handled, to cease  
19 immediately distribution of the article;

20 “(C) to recall the article;

21 “(D) in consultation with the Secretary, to  
22 provide notice of the finding of the Secretary to  
23 all consumers to which the article was, or may  
24 have been, distributed; or

1                   “(E) to notify State and local public health  
2                   officials.

3                   “(2) MANDATORY ACTIONS.—If the appropriate  
4                   person referred to in paragraph (1) does not carry  
5                   out the actions described in that paragraph with re-  
6                   spect to an article within the time period and in the  
7                   manner prescribed by the Secretary, the Secretary—

8                   “(A) shall require the person—

9                   “(i) to immediately cease distribution  
10                  of the article; and

11                  “(ii) to immediately make the notifica-  
12                  tion described in paragraph (1)(B); and

13                  “(B) may take control or possession of the  
14                  article.

15                  “(3) NOTICE TO CONSUMERS AND HEALTH OF-  
16                  FICIALS.—The Secretary shall, as the Secretary de-  
17                  termines to be necessary, provide notice of the find-  
18                  ing of the Secretary under paragraph (1) to con-  
19                  sumers to which the article was, or may have been,  
20                  distributed and to appropriate State and local public  
21                  health officials.

22                  “(4) NONDISTRIBUTION BY NOTIFIED PER-  
23                  SONS.—A person that transports, stores, distributes,  
24                  or otherwise handles the article, or to which the arti-  
25                  cle has been transported, sold, distributed, or other-

1 wise handled, and that is notified under paragraph  
2 (1)(B) or (2)(B) shall cease immediately distribution  
3 of the article.

4 “(5) AVAILABILITY OF RECORDS TO SEC-  
5 RETARY.—Each appropriate person referred to in  
6 paragraph (1) that transported, stored, distributed,  
7 or otherwise handled an article shall make available  
8 to the Secretary information necessary to carry out  
9 this subsection, as determined by the Secretary, re-  
10 garding—

11 “(A) persons that transport, store, dis-  
12 tribute, or otherwise handle the article; and

13 “(B) persons to which the article has been  
14 transported, sold, distributed, or otherwise han-  
15 dled.

16 “(c) INFORMAL HEARINGS ON ORDERS.—

17 “(1) IN GENERAL.—The Secretary shall provide  
18 a person subject to an order under subsection (b)  
19 with an opportunity for an informal hearing (in ac-  
20 cordance with such rules or regulations as the Sec-  
21 retary shall prescribe) on—

22 “(A) the actions required by the order; and

23 “(B) any reasons why the article that is  
24 the subject of the order should not be recalled.

1           “(2) TIMING OF HEARINGS.—The Secretary  
2           shall hold a hearing under paragraph (1) as soon as  
3           practicable, but not later than 2 business days, after  
4           the date of issuance of the order.

5           “(d) POST-HEARING RECALL ORDERS.—

6           “(1) AMENDMENT OF ORDERS.—If, after pro-  
7           viding an opportunity for an informal hearing under  
8           subsection (c), the Secretary determines that there is  
9           a reasonable probability that human consumption of  
10          the article that is the subject of an order under sub-  
11          section (b) presents a threat to public health, the  
12          Secretary may, as the Secretary determines to be  
13          necessary—

14               “(A) amend the order under subsection  
15               (b)—

16                       “(i) to require recall of the article or  
17                       other appropriate action; and

18                       “(ii) to specify a timetable during  
19                       which the recall shall occur;

20               “(B) require periodic reports to the Sec-  
21               retary describing the progress of the recall;

22               “(C) provide notice of the recall to con-  
23               sumers to which the article was, or may have  
24               been, distributed; or

1 “(D) take any combination of actions de-  
2 scribed in subparagraphs (A) through (C).

3 “(2) VACATION OF ORDERS.—If, after providing  
4 an opportunity for an informal hearing under sub-  
5 section (c), the Secretary determines that adequate  
6 grounds do not exist to continue the actions required  
7 by the order, the Secretary shall vacate the order.

8 “(e) REMEDIES NOT EXCLUSIVE.—The remedies au-  
9 thorized by this section shall be in addition to any other  
10 remedies that may be available.

11 **“SEC. 412. REFUSAL OR WITHDRAWAL OF INSPECTION OF**  
12 **ESTABLISHMENTS.**

13 “(a) IN GENERAL.—The Secretary may, for such pe-  
14 riod, or indefinitely, as the Secretary considers necessary  
15 to carry out this Act, refuse to provide or withdraw inspec-  
16 tion under title I with respect to an establishment if the  
17 Secretary determines, after opportunity for a hearing on  
18 the record is provided to the applicant for, or recipient  
19 of, inspection, that the applicant or recipient, or any per-  
20 son responsibly connected with the applicant or recipient  
21 (within the meaning of section 401), has committed a will-  
22 ful violation or repeated violations of this Act (including  
23 a regulation promulgated under this Act).

24 “(b) DENIAL OR SUSPENSION OF INSPECTION PEND-  
25 ING HEARING.—The Secretary may deny or suspend in-

1   spection under title I, pending opportunity for an expe-  
2   dited hearing, with respect to an action under subsection  
3   (a), if the Secretary determines that the denial or suspen-  
4   sion is in the public interest to protect the health or wel-  
5   fare of consumers or to ensure the effective performance  
6   of an official duty under this Act.

7       “(c) JUDICIAL REVIEW.—

8           “(1) IN GENERAL.—A determination and order  
9       of the Secretary with respect to the refusal or with-  
10      drawal of inspection under this section shall be final  
11      unless, not later than 30 days after the effective  
12      date of the order, the affected applicant for, or re-  
13      cipient of, inspection—

14           “(A) files a petition for judicial review of  
15      the order; and

16           “(B) simultaneously sends a copy of the  
17      petition by certified mail to the Secretary.

18           “(2) REFUSAL OR WITHDRAWAL OF INSPEC-  
19      TION PENDING REVIEW.—Inspection shall be refused  
20      or withdrawn as of the effective date of the order  
21      pending any judicial review of the order unless the  
22      Secretary directs otherwise.

23           “(3) VENUE; RECORD.—Judicial review of the  
24      order shall be—

25           “(A) in—



1 “(i) the United States court of ap-  
2 peals for the circuit in which the applicant  
3 for, or recipient of, inspection resides or  
4 has its principal place of business; or

5 “(ii) the United States Court of Ap-  
6 peals for the District of Columbia Circuit;  
7 and

8 “(B) on the record on which the deter-  
9 mination and order are based.

10 “(d) REMEDIES NOT EXCLUSIVE.—The remedies au-  
11 thorized by this section shall be in addition to any other  
12 remedies that may be available.

13 **“SEC. 413. CIVIL PENALTIES.**

14 “(a) IN GENERAL.—

15 “(1) ASSESSMENT.—The Secretary may assess  
16 against a person that violates this Act (including a  
17 regulation promulgated or order issued under this  
18 Act) a civil penalty for each violation of not more  
19 than \$100,000.

20 “(2) SEPARATE OFFENSES.—Each violation  
21 and each day during which the violation continues  
22 shall be considered to be a separate offense.

23 “(3) NOTICE AND OPPORTUNITY FOR HEAR-  
24 ING.—The Secretary shall not assess a civil penalty  
25 under this section against a person unless the person

1 is given notice and opportunity for a hearing on the  
2 record before the Secretary in accordance with sec-  
3 tions 554 and 556 of title 5, United States Code.

4 “(4) DETERMINATION OF CIVIL PENALTY  
5 AMOUNT.—The amount of a civil penalty under this  
6 section—

7 “(A) shall be assessed by the Secretary by  
8 written order, taking into account—

9 “(i) the gravity of the violation;

10 “(ii) the degree of culpability of the  
11 person;

12 “(iii) the size and type of the business  
13 of the person; and

14 “(iv) any history of prior offenses by  
15 the person under this Act; and

16 “(B) shall be reviewed only in accordance  
17 with subsection (b).

18 “(b) JUDICIAL REVIEW.—

19 “(1) IN GENERAL.—An order assessing a civil  
20 penalty against a person under subsection (a) shall  
21 be final unless the person—

22 “(A) not later than 30 days after the effec-  
23 tive date of the order, files a petition for judi-  
24 cial review of the order in—

1 “(i) the United States court of ap-  
2 peals for the circuit in which the person re-  
3 sides or has its principal place of business;  
4 or

5 “(ii) the United States Court of Ap-  
6 peals for the District of Columbia Circuit;  
7 and

8 “(B) simultaneously sends a copy of the  
9 petition by certified mail to the Secretary.

10 “(2) FILING OF COPY OF RECORD.—The Sec-  
11 retary shall promptly file in the court a certified  
12 copy of the record on which the order was issued.

13 “(c) COLLECTION ACTIONS FOR FAILURE TO PAY  
14 ASSESSMENT.—

15 “(1) REFERRAL TO ATTORNEY GENERAL.—If a  
16 person fails to pay a civil penalty assessed under  
17 subsection (a) after the order assessing the civil pen-  
18 alty has become a final order, or after the court of  
19 appeals has entered final judgment in favor of the  
20 Secretary, the Secretary shall refer the matter to the  
21 Attorney General.

22 “(2) ACTION BY ATTORNEY GENERAL.—The  
23 Attorney General shall bring a civil action to recover  
24 the amount of the civil penalty in United States dis-  
25 trict court.

1           “(3) SCOPE OF REVIEW.—In a civil action  
2           under paragraph (2), the validity and appropriate-  
3           ness of the order of the Secretary assessing the civil  
4           penalty shall not be subject to review.

5           “(d) REFUSAL OR WITHDRAWAL OF INSPECTION  
6           PENDING PAYMENT.—If a person fails to pay the amount  
7           of a civil penalty after the order assessing the civil penalty  
8           has become a final order, the Secretary may refuse to pro-  
9           vide or withdraw inspection under title I of the person  
10          until the civil penalty is paid or until the Secretary directs  
11          otherwise.

12          “(e) PENALTIES IN LIEU OF OTHER ACTIONS.—  
13          Nothing in this Act requires the Secretary to report for  
14          prosecution, or for the commencement of an action, any  
15          violation of this Act in any case in which the Secretary  
16          believes that the public interest will be adequately served  
17          by the assessment of a civil penalty under this section.

18          “(f) REMEDIES NOT EXCLUSIVE.—The remedies au-  
19          thorized by this section shall be in addition to any other  
20          remedies that may be available.”.

21          (b) CONFORMING AMENDMENTS.—

22                 (1) Section 1 of the Federal Meat Inspection  
23                 Act (21 U.S.C. 601) is amended by adding at the  
24                 end the following:

1       “(x) PERSON.—The term ‘person’ means any indi-  
2       vidual, partnership, corporation, association, or other busi-  
3       ness unit.”.

4               (2) The Federal Meat Inspection Act (21  
5       U.S.C. 601 et seq.) is amended—

6               (A) by striking “person, firm, or corpora-  
7       tion” each place it appears and inserting “per-  
8       son”;

9               (B) by striking “persons, firms, and cor-  
10       porations” each place it appears and inserting  
11       “persons”; and

12              (C) by striking “persons, firms, or corpora-  
13       tions” each place it appears and inserting “per-  
14       sons”.

15   **SEC. 3. FOOD SAFETY ENFORCEMENT FOR POULTRY AND**  
16               **POULTRY FOOD PRODUCTS.**

17       The Poultry Products Inspection Act (21 U.S.C. 451  
18       et seq.) is amended—

19              (1) in the first sentence of section 5(c)(1) (21  
20       U.S.C. 454(c)(1))—

21              (A) by striking “, by thirty days prior to  
22       the expiration of two years after enactment of  
23       the Wholesome Poultry Products Act,”; and

24              (B) by striking “sections 1–4, 6–10, and  
25       12–22 of this Act” and inserting “sections 1

1 through 4, 6 through 10, 12 through 22, and  
2 31 through 33”; and

3 (2) by adding at the end the following:

4 **“SEC. 31. NOTIFICATION, NONDISTRIBUTION, AND RECALL**  
5 **OF ADULTERATED OR MISBRANDED ARTI-**  
6 **CLES.**

7 “(a) NOTIFICATION TO SECRETARY OF VIOLATION.—

8 “(1) IN GENERAL.—A person (other than a  
9 household consumer) that has reason to believe that  
10 any poultry or poultry product (referred to in this  
11 section as an ‘article’) transported, stored, distrib-  
12 uted, or otherwise handled by the person is adulter-  
13 ated or misbranded shall, as soon as practicable, no-  
14 tify the Secretary of the identity and location of the  
15 article.

16 “(2) MANNER OF NOTIFICATION.—Notification  
17 under paragraph (1) shall be made in such manner  
18 and by such means as the Secretary may require by  
19 regulation.

20 “(b) RECALL AND CONSUMER NOTIFICATION.—

21 “(1) VOLUNTARY ACTIONS.—On receiving noti-  
22 fication under subsection (a) or by other means, if  
23 the Secretary finds that an article is adulterated or  
24 misbranded and that there is a reasonable prob-  
25 ability that human consumption of the article would

1 present a threat to public health (as determined by  
2 the Secretary), the Secretary shall provide all appro-  
3 priate persons (as determined by the Secretary),  
4 that transported, stored, distributed, or otherwise  
5 handled the article with an opportunity—

6 “(A) to cease distribution of the article;

7 “(B) to notify all persons that transport,  
8 store, distribute, or otherwise handle the article,  
9 or to which the article has been transported,  
10 sold, distributed, or otherwise handled, to cease  
11 immediately distribution of the article;

12 “(C) to recall the article;

13 “(D) in consultation with the Secretary, to  
14 provide notice of the finding of the Secretary to  
15 all consumers to which the article was, or may  
16 have been, distributed; or

17 “(E) to notify State and local public health  
18 officials.

19 “(2) MANDATORY ACTIONS.—If the appropriate  
20 person referred to in paragraph (1) does not carry  
21 out the actions described in that paragraph with re-  
22 spect to an article within the time period and in the  
23 manner prescribed by the Secretary, the Secretary—

24 “(A) shall require the person—

1 “(i) to immediately cease distribution  
2 of the article; and

3 “(ii) to immediately make the notifica-  
4 tion described in paragraph (1)(B); and

5 “(B) may take control or possession of the  
6 article.

7 “(3) NOTICE TO CONSUMERS AND HEALTH OF-  
8 FICIALS.—The Secretary shall, as the Secretary de-  
9 termines to be necessary, provide notice of the find-  
10 ing of the Secretary under paragraph (1) to con-  
11 sumers to which the article was, or may have been,  
12 distributed and to appropriate State and local health  
13 officials.

14 “(4) NONDISTRIBUTION BY NOTIFIED PER-  
15 SONS.—A person that transports, stores, distributes,  
16 or otherwise handles the article, or to which the arti-  
17 cle has been transported, sold, distributed, or other-  
18 wise handled, and that is notified under paragraph  
19 (1)(B) or (2)(B) shall cease immediately distribution  
20 of the article.

21 “(5) AVAILABILITY OF RECORDS TO SEC-  
22 RETARY.—Each appropriate person referred to in  
23 paragraph (1) that transported, stored, distributed,  
24 or otherwise handled an article shall make available  
25 to the Secretary information necessary to carry out



1       this subsection, as determined by the Secretary, re-  
2       garding—

3               “(A) persons that transport, store, dis-  
4       tribute, or otherwise handle the article; and

5               “(B) persons to which the article has been  
6       transported, sold, distributed, or otherwise han-  
7       dled.

8       “(c) INFORMAL HEARINGS ON ORDERS.—

9               “(1) IN GENERAL.—The Secretary shall provide  
10      a person subject to an order under subsection (b)  
11      with an opportunity for an informal hearing (in ac-  
12      cordance with such rules or regulations as the Sec-  
13      retary shall prescribe) on—

14              “(A) the actions required by the order; and

15              “(B) any reasons why the article that is  
16      the subject of the order should not be recalled.

17              “(2) TIMING OF HEARINGS.—The Secretary  
18      shall hold a hearing under paragraph (1) as soon as  
19      practicable, but not later than 2 business days, after  
20      the date of issuance of the order.

21       “(d) POST-HEARING RECALL ORDERS.—

22              “(1) AMENDMENT OF ORDERS.—If, after pro-  
23      viding an opportunity for an informal hearing under  
24      subsection (c), the Secretary determines that there is  
25      a reasonable probability that human consumption of

1 the article that is the subject of an order under sub-  
2 section (b) presents a threat to public health, the  
3 Secretary may, as the Secretary determines to be  
4 necessary—

5 “(A) amend the order under subsection  
6 (b)—

7 “(i) to require recall of the article or  
8 other appropriate action; and

9 “(ii) to specify a timetable during  
10 which the recall shall occur;

11 “(B) require periodic reports to the Sec-  
12 retary describing the progress of the recall; or

13 “(C) provide notice of the recall to con-  
14 sumers to which the article was, or may have  
15 been, distributed.

16 “(2) VACATION OF ORDERS.—If, after providing  
17 an opportunity for an informal hearing under sub-  
18 section (c), the Secretary determines that adequate  
19 grounds do not exist to continue the actions required  
20 by the order, the Secretary shall vacate the order.

21 “(e) REMEDIES NOT EXCLUSIVE.—The remedies au-  
22 thorized by this section shall be in addition to any other  
23 remedies that may be available.

1   **“SEC. 32. REFUSAL OR WITHDRAWAL OF INSPECTION OF**  
2                   **ESTABLISHMENTS.**

3           “(a) IN GENERAL.—The Secretary may, for such pe-  
4 riod, or indefinitely, as the Secretary considers necessary  
5 to carry out this Act, refuse to provide or withdraw inspec-  
6 tion under this Act with respect to an establishment if the  
7 Secretary determines, after opportunity for a hearing on  
8 the record is provided to the applicant for, or recipient  
9 of, inspection, that the applicant or recipient, or any per-  
10 son responsibly connected with the applicant or recipient  
11 (within the meaning of section 18(a)), has committed a  
12 willful violation or repeated violations of this Act (includ-  
13 ing a regulation promulgated under this Act).

14           “(b) DENIAL OR SUSPENSION OF INSPECTION PEND-  
15 ING HEARING.—The Secretary may deny or suspend in-  
16 spection under this Act, pending opportunity for an expe-  
17 dited hearing, with respect to an action under subsection  
18 (a), if the Secretary determines that the denial or suspen-  
19 sion is in the public interest to protect the health or wel-  
20 fare of consumers or to ensure the effective performance  
21 of an official duty under this Act.

22           “(c) JUDICIAL REVIEW.—

23           “(1) IN GENERAL.—A determination and order  
24 of the Secretary with respect to the refusal or with-  
25 drawal of inspection under this section shall be final  
26 unless, not later than 30 days after the effective

1 date of the order, the affected applicant for, or re-  
2 cipient of, inspection—

3 “(A) files a petition for judicial review of  
4 the order; and

5 “(B) simultaneously sends a copy of the  
6 petition by certified mail to the Secretary.

7 “(2) REFUSAL OR WITHDRAWAL OF INSPEC-  
8 TION PENDING REVIEW.—Inspection shall be refused  
9 or withdrawn as of the effective date of the order  
10 pending any judicial review of the order unless the  
11 Secretary directs otherwise.

12 “(3) VENUE; RECORD.—Judicial review of the  
13 order shall be—

14 “(A) in—

15 “(i) the United States court of ap-  
16 peals for the circuit in which the applicant  
17 for, or recipient of, inspection resides or  
18 has its principal place of business; or

19 “(ii) the United States Court of Ap-  
20 peals for the District of Columbia Circuit;  
21 and

22 “(B) on the record on which the deter-  
23 mination and order are based.

1 “(d) REMEDIES NOT EXCLUSIVE.—The remedies au-  
2 thorized by this section shall be in addition to any other  
3 remedies that may be available.

4 **“SEC. 33. CIVIL PENALTIES.**

5 “(a) IN GENERAL.—

6 “(1) ASSESSMENT.—The Secretary may assess  
7 against a person that violates this Act (including a  
8 regulation promulgated or order issued under this  
9 Act) a civil penalty for each violation of not more  
10 than \$100,000.

11 “(2) SEPARATE OFFENSES.—Each violation  
12 and each day during which the violation continues  
13 shall be considered to be a separate offense.

14 “(3) NOTICE AND OPPORTUNITY FOR HEAR-  
15 ING.—The Secretary shall not assess a civil penalty  
16 under this section against a person unless the person  
17 is given notice and opportunity for a hearing on the  
18 record before the Secretary in accordance with sec-  
19 tions 554 and 556 of title 5, United States Code.

20 “(4) DETERMINATION OF CIVIL PENALTY  
21 AMOUNT.—The amount of a civil penalty under this  
22 section—

23 “(A) shall be assessed by the Secretary by  
24 written order, taking into account—

25 “(i) the gravity of the violation;

1 “(ii) the degree of culpability of the  
2 person;

3 “(iii) the size and type of the business  
4 of the person; and

5 “(iv) any history of prior offenses by  
6 the person under this Act; and

7 “(B) shall be reviewed only in accordance  
8 with subsection (b).

9 “(b) JUDICIAL REVIEW.—

10 “(1) IN GENERAL.—An order assessing a civil  
11 penalty against a person under subsection (a) shall  
12 be final unless the person—

13 “(A) not later than 30 days after the effec-  
14 tive date of the order, files a petition for judi-  
15 cial review of the order in—

16 “(i) the United States court of ap-  
17 peals for the circuit in which the person re-  
18 sides or has its principal place of business;  
19 or

20 “(ii) the United States Court of Ap-  
21 peals for the District of Columbia Circuit;  
22 and

23 “(B) simultaneously sends a copy of the  
24 petition by certified mail to the Secretary.

1           “(2) FILING OF COPY OF RECORD.—The Sec-  
2       retary shall promptly file in the court a certified  
3       copy of the record on which the order was issued.

4       “(c) COLLECTION ACTIONS FOR FAILURE TO PAY  
5       ASSESSMENT.—

6           “(1) REFERRAL TO ATTORNEY GENERAL.—If a  
7       person fails to pay a civil penalty assessed under  
8       subsection (a) after the order assessing the civil pen-  
9       alty has become a final order, or after the court of  
10      appeals has entered final judgment in favor of the  
11      Secretary, the Secretary shall refer the matter to the  
12      Attorney General.

13          “(2) ACTION BY ATTORNEY GENERAL.—The  
14      Attorney General shall bring a civil action to recover  
15      the amount of the civil penalty in United States dis-  
16      trict court.

17          “(3) SCOPE OF REVIEW.—In a civil action  
18      under paragraph (2), the validity and appropriate-  
19      ness of the order of the Secretary assessing the civil  
20      penalty shall not be subject to review.

21          “(d) REFUSAL OR WITHDRAWAL OF INSPECTION  
22      PENDING PAYMENT.—If a person fails to pay the amount  
23      of a civil penalty after the order assessing the civil penalty  
24      has become a final order, the Secretary may refuse to pro-  
25      vide or withdraw inspection under this Act of the person

1 until the civil penalty is paid or until the Secretary directs  
2 otherwise.

3 “(e) PENALTIES IN LIEU OF OTHER ACTIONS.—  
4 Nothing in this Act requires the Secretary to report for  
5 prosecution, or for the commencement of an action, any  
6 violation of this Act in any case in which the Secretary  
7 believes that the public interest will be adequately served  
8 by the assessment of a civil penalty under this section.

9 “(f) REMEDIES NOT EXCLUSIVE.—The remedies au-  
10 thorized by this section shall be in addition to any other  
11 remedies that may be available.”.

12 **SEC. 4. NOTIFICATION, NONDISTRIBUTION, AND RECALL**  
13 **OF ADULTERATED OR MISBRANDED ARTI-**  
14 **CLES OF FOOD.**

15 (a) PROHIBITED ACTS.—Section 301 of the Federal  
16 Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amend-  
17 ed by adding at the end the following:

18 “(oo)(1) The failure to notify the Secretary in viola-  
19 tion of section 311(a).

20 “(2) The failure to comply with—

21 “(A) an order issued under section 311(b) fol-  
22 lowing any hearing requested under section 311(c);  
23 or

24 “(B) an amended order issued under section  
25 311(d)(1).”.



1 (b) NOTIFICATION, NONDISTRIBUTION, AND RECALL  
2 OF ADULTERATED OR MISBRANDED ARTICLES OF FOOD;  
3 CIVIL PENALTIES RELATING TO FOODS.—Chapter III of  
4 the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331  
5 et seq.) is amended by adding at the end the following:

6 **“SEC. 311. NOTIFICATION, NONDISTRIBUTION, AND RECALL**  
7 **OF ADULTERATED OR MISBRANDED ARTI-**  
8 **CLES OF FOOD.**

9 “(a) NOTIFICATION TO SECRETARY OF VIOLATION.—

10 “(1) IN GENERAL.—A person (other than a  
11 household consumer or other individual who is the  
12 intended consumer of an article of food) that has  
13 reason to believe that an article of food when intro-  
14 duced into or while in interstate commerce, or while  
15 held for sale (regardless of whether the first sale)  
16 after shipment in interstate commerce, is adulter-  
17 ated or misbranded in a manner that, if consumed,  
18 may result in illness or injury shall, as soon as prac-  
19 ticable, notify the Secretary of the identity and loca-  
20 tion of the article.

21 “(2) MANNER OF NOTIFICATION.—Notification  
22 under paragraph (1) shall be made in such manner  
23 and by such means as the Secretary may require by  
24 regulation.

25 “(b) RECALL AND CONSUMER NOTIFICATION.—

1           “(1) VOLUNTARY ACTIONS.—On receiving noti-  
2           fication under subsection (a) or by other means, if  
3           the Secretary finds that an article of food when in-  
4           troduced into or while in interstate commerce, or  
5           while held for sale (regardless of whether the first  
6           sale) after shipment in interstate commerce, is adul-  
7           terated or misbranded in a manner that, if con-  
8           sumed, may result in illness or injury (as determined  
9           by the Secretary), the Secretary shall provide all ap-  
10          propriate persons (including the manufacturer, im-  
11          porter, distributor, or retailer of the article) with an  
12          opportunity (as determined by the Secretary)—

13                 “(A) to cease distribution of the article;

14                 “(B) to notify all persons—

15                         “(i) that produce, manufacture, pack,  
16                         process, prepare, treat, package, distribute,  
17                         or hold the article, to cease immediately  
18                         those activities with respect to the article;  
19                         or

20                         “(ii) to which the article has been dis-  
21                         tributed, transported, or sold, to cease im-  
22                         mediately distribution of the article;

23                 “(C) to recall the article;

24                 “(D) in consultation with the Secretary, to  
25          provide notice of the finding of the Secretary to

1 all consumers to which the article was, or may  
2 have been, distributed and to appropriate State  
3 and local health officials; or

4 “(E) to notify State and local public health  
5 officials.

6 “(2) MANDATORY ACTIONS.—If the appropriate  
7 person referred to in paragraph (1) does not carry  
8 out the actions described in that paragraph with re-  
9 spect to an article within the time period and in the  
10 manner prescribed by the Secretary, the Secretary—

11 “(A) shall require the person—

12 “(i) to immediately cease distribution  
13 of the article; and

14 “(ii) to immediately make the notifica-  
15 tion described in paragraph (1)(B); and

16 “(B) may take control or possession of the  
17 article.

18 “(3) NOTICE TO CONSUMERS AND HEALTH OF-  
19 FICIALS.—The Secretary shall, as the Secretary de-  
20 termines to be necessary, provide notice of the find-  
21 ing of the Secretary under paragraph (1) to con-  
22 sumers to which the article was, or may have been,  
23 distributed and to appropriate State and local health  
24 officials.

25 “(c) HEARINGS ON ORDERS.—

1           “(1) IN GENERAL.—The Secretary shall provide  
2           a person subject to an order under subsection (b)  
3           with an opportunity for a hearing on—

4                   “(A) the actions required by the order; and

5                   “(B) any reasons why the article of food  
6           that is the subject of the order should not be  
7           recalled.

8           “(2) TIMING OF HEARINGS.—The Secretary  
9           shall hold a hearing under paragraph (1) as soon as  
10          practicable, but not later than 2 business days, after  
11          the date of issuance of the order.

12          “(d) POST-HEARING RECALL ORDERS.—

13               “(1) AMENDMENT OF ORDERS.—If, after pro-  
14          viding an opportunity for a hearing under subsection  
15          (c), the Secretary determines that an article of food  
16          when introduced into or while in interstate com-  
17          merce, or while held for sale (regardless of whether  
18          the first sale) after shipment in interstate commerce,  
19          is adulterated or misbranded in a manner that, if  
20          consumed, may result in illness or injury, the Sec-  
21          retary may, as the Secretary determines to be nec-  
22          essary—

23                   “(A) amend the order under subsection  
24                  (b)—

1 “(i) to require recall of the article or  
2 other appropriate action; and

3 “(ii) to specify a timetable during  
4 which the recall shall occur;

5 “(B) require periodic reports to the Sec-  
6 retary describing the progress of the recall; or

7 “(C) provide notice of the recall to con-  
8 sumers to which the article was, or may have  
9 been, distributed.

10 “(2) VACATION OF ORDERS.—If, after providing  
11 an opportunity for a hearing under subsection (c),  
12 the Secretary determines that adequate grounds do  
13 not exist to continue the actions required by the  
14 order, the Secretary shall vacate the order.

15 “(e) REMEDIES NOT EXCLUSIVE.—The remedies au-  
16 thorized by this section shall be in addition to any other  
17 remedies that may be available.

18 **“SEC. 312. CIVIL PENALTIES RELATING TO FOODS.**

19 “(a) IN GENERAL.—

20 “(1) ASSESSMENT.—The Secretary may assess  
21 against a person that commits an act prohibited by  
22 section 301 with respect to an article of food a civil  
23 penalty for each such act of not more than—

24 “(A) \$100,000, in the case of an indi-  
25 vidual; and

1           “(B) \$500,000, in the case of any other  
2           person.

3           “(2) SEPARATE OFFENSES.—Each prohibited  
4           act and each day during which the act continues  
5           shall be considered to be a separate offense.

6           “(3) NOTICE AND OPPORTUNITY FOR HEAR-  
7           ING.—The Secretary shall not assess a civil penalty  
8           under this section against a person unless the person  
9           is given notice and opportunity for a hearing on the  
10          record before the Secretary in accordance with sec-  
11          tions 554 and 556 of title 5, United States Code.

12          “(4) DETERMINATION OF CIVIL PENALTY  
13          AMOUNT.—The amount of a civil penalty under this  
14          section—

15               “(A) shall be assessed by the Secretary by  
16               written order, taking into account—

17                       “(i) the gravity of the violation;

18                       “(ii) the degree of culpability of the  
19                       person;

20                       “(iii) the size and type of the business  
21                       of the person; and

22                       “(iv) any history of prior offenses by  
23                       the person; and

24               “(B) shall be reviewed only in accordance  
25               with subsection (b).

1 “(b) JUDICIAL REVIEW.—

2 “(1) IN GENERAL.—An order assessing a civil  
3 penalty against a person under subsection (a) shall  
4 be final unless the person—

5 “(A) not later than 30 days after the effective date of the order, files a petition for judicial review of the order in—

8 “(i) the United States court of appeals for the circuit in which the person resides or has its principal place of business;  
9  
10  
11 or

12 “(ii) the United States Court of Appeals for the District of Columbia Circuit;  
13  
14 and

15 “(B) simultaneously sends a copy of the petition by certified mail to the Secretary.

17 “(2) FILING OF COPY OF RECORD.—The Secretary shall promptly file in the court a certified  
18  
19 copy of the record on which the order was issued.

20 “(3) STANDARD OF REVIEW.—The findings of  
21 the Secretary relating to the order shall be set aside  
22 only if the findings are found to be unsupported by  
23 substantial evidence on the record as a whole.

24 “(c) COLLECTION ACTIONS FOR FAILURE TO PAY  
25 ASSESSMENT.—

1           “(1) REFERRAL TO ATTORNEY GENERAL.—If a  
2           person fails to pay a civil penalty assessed under  
3           subsection (a) after the order assessing the civil pen-  
4           alty has become a final order, or after the court of  
5           appeals has entered final judgment in favor of the  
6           Secretary, the Secretary may refer the matter to the  
7           Attorney General.

8           “(2) ACTION BY ATTORNEY GENERAL.—The  
9           Attorney General shall bring a civil action to recover  
10          the amount of the civil penalty in United States dis-  
11          trict court.

12          “(3) SCOPE OF REVIEW.—In a civil action  
13          under paragraph (2), the validity and appropriate-  
14          ness of the order of the Secretary assessing the civil  
15          penalty shall not be subject to review.

16          “(d) PENALTIES DEPOSITED IN TREASURY.—All  
17          amounts collected as civil penalties under this section shall  
18          be deposited in the Treasury of the United States.

19          “(e) PENALTIES IN LIEU OF OTHER ACTIONS.—  
20          Nothing in this Act requires the Secretary to report for  
21          prosecution, or for the commencement of any libel or in-  
22          junction proceeding, any violation of this Act in any case  
23          in which the Secretary believes that the public interest will  
24          be adequately served by the assessment of a civil penalty  
25          under this section.



1       “(f) REMEDIES NOT EXCLUSIVE.—The remedies au-  
2   thorized by this section shall be in addition to any other  
3   remedies that may be available.”.